

Assembly Bill No. 339

CHAPTER 619

An act to amend Section 1367.205 of, to add Sections 1367.41 and 1367.42 to, and to add and repeal Section 1342.71 of, the Health and Safety Code, and to amend Section 10123.192 of, to add Section 10123.201 to, and to add and repeal Section 10123.193 of, the Insurance Code, relating to health care coverage.

[Approved by Governor October 8, 2015. Filed with
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LEGISLATIVE COUNSEL'S DIGEST

AB 339, Gordon. Health care coverage: outpatient prescription drugs.

(1) Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan or insurer that provides prescription drug benefits and maintains one or more drug formularies to make specified information regarding the formularies available to the public and other specified entities. Existing law also specifies requirements for those plans and insurers regarding coverage and cost sharing of specified prescription drugs.

This bill would prohibit the formulary or formularies for outpatient prescription drugs maintained by a health care service plan or health insurer from discouraging the enrollment of individuals with health conditions and from reducing the generosity of the benefit for enrollees or insureds with a particular condition. The bill, until January 1, 2020, would provide that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription shall not exceed \$250 for a supply of up to 30 days, except as specified, and would prohibit, for a nongrandfathered individual or small group plan contract or policy, the annual deductible for outpatient drugs from exceeding a specified amount. The bill would make these cost-sharing limits applicable only to covered outpatient prescription drugs that constitute essential health benefits, as defined. The bill would require a plan contract or policy to cover a single-tablet prescription drug regimen for combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, as specified. The bill, until January 1, 2020, would require a nongrandfathered individual or small group plan contract or policy to use specified definitions for each tier of a drug formulary. The bill would make related findings and declarations.

This bill would require a health care service plan contract or health insurance policy that provides coverage for outpatient prescription drugs to provide coverage for medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary, and, for an insurer, would require copayments, coinsurance, and other cost sharing for outpatient prescription drugs to be reasonable.

This bill would make these provisions applicable to nongrandfathered health care service plan contracts or health insurance policies that are offered, renewed, or amended on or after January 1, 2017.

(2) Existing law requires every health care service plan that provides prescription drug benefits to maintain specified information that is required to be made available to the Director of the Department of Managed Health Care upon request.

This bill would also impose these requirements on a health insurer that provides prescription drug benefits, as provided. The bill would authorize an insurer to require step therapy, as defined, when more than one drug is appropriate for the treatment of a medical condition, subject to specified requirements. The bill, with regard to an insured changing policies, would prohibit a new insurer from requiring the insured to repeat step therapy when that person is already being treated for a medical condition by a prescription drug, as specified. For plan years commencing on or after January 1, 2017, the bill, except as specified, would require a plan or insurer that provides essential health benefits to allow an enrollee or insured to access his or her prescription drug benefits at an in-network retail pharmacy, and would authorize a nongrandfathered individual or small group plan or insurer to charge an enrollee or insured a different cost sharing for obtaining a covered drug at a retail pharmacy, and would require that cost-sharing amount to count towards the plan's or insurer's annual out-of-pocket limitation, as specified.

This bill, commencing January 1, 2017, would require a plan or insurer to maintain a pharmacy and therapeutics committee that is responsible for developing, maintaining, and overseeing any drug formulary list, as provided. The bill would require the committee to, among other things, evaluate and analyze treatment protocols and procedures related to the plan's or insurer's drug formulary at least annually.

(3) Existing law requires the Department of Managed Health Care and the Department of Insurance to jointly develop a standard formulary template by January 1, 2017, and requires plans and insurers to use that template to display formularies, as specified. Existing law requires the standard formulary template to include specified information.

This bill would require the standard formulary template to include additional specified information, including which medications are covered, including both generic and brand name.

(4) Because a willful violation of the bill's requirements relative to health care service plans would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 1342.71 is added to the Health and Safety Code, to read:

1342.71. (a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered health care service plan contract that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section. The cost-sharing limits established by this section apply only to outpatient prescription drugs covered by the contract that constitute essential health benefits, as defined in Section 1367.005.

(c) A health care service plan contract that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this chapter.

(d) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health care service plan shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for enrollees with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet

regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(e) (1) With respect to an individual or group health care service plan contract subject to Section 1367.006, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars (\$250), except as provided in paragraphs (2) and (3).

(2) With respect to products with actuarial value at, or equivalent to, the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars (\$500), except as provided in paragraph (3).

(3) For a health care service plan contract that is a “high deductible health plan” under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision shall apply only once an enrollee’s deductible has been satisfied for the year.

(4) For a nongrandfathered individual or small group health care service plan contract, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.

(5) For purposes of paragraphs (1) and (2), “any other form of cost sharing” shall not include deductible.

(f) (1) If a health care service plan contract for a nongrandfathered individual or small group product maintains a drug formulary grouped into tiers that includes a fourth tier, a health care service plan contract shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health care service plan’s pharmacy and therapeutics committee based on safety, efficacy, and cost.

(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health care service plan’s pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.

(D) Tier four shall consist of drugs that are biologics, drugs that the FDA or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the enrollee to have special training or clinical monitoring for self-administration, or drugs that cost the health plan more than six hundred dollars (\$600) net of rebates for a one-month supply.

(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the health care service plan shall take into account the other provisions of this section and this chapter.

(3) A health care service plan contract may maintain a drug formulary with fewer than four tiers.

(4) This section shall not be construed to limit a health care service plan from placing any drug in a lower tier.

(g) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(h) This section shall not be construed to require a health care service plan to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

(i) This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.

(j) In the provision of outpatient prescription drug coverage, a health care service plan may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this chapter.

(k) This section shall not apply to a health care service plan that contracts with the State Department of Health Care Services.

(l) This section shall remain in effect only until January 1, 2020, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2020, deletes or extends that date.

SEC. 2. Section 1342.71 is added to the Health and Safety Code, to read:

1342.71. (a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered health care service plan contract that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section.

(c) A health care service plan contract that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this chapter.

(d) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health care service plan shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for enrollees with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(e) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(f) This section shall not be construed to require a health care service plan to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

(g) This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.

(h) In the provision of outpatient prescription drug coverage, a health care service plan may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this chapter.

(i) This section shall not apply to a health care service plan that contracts with the State Department of Health Care Services.

(j) This section shall become operative on January 1, 2020.

SEC. 3. Section 1367.41 is added to the Health and Safety Code, immediately following Section 1367.4, to read:

1367.41. (a) Commencing January 1, 2017, a health care service plan shall maintain a pharmacy and therapeutics committee that shall be responsible for developing, maintaining, and overseeing any drug formulary list. If the plan delegates responsibility for the formulary to any entity, the obligation of the plan to comply with this chapter shall not be waived.

(b) The pharmacy and therapeutics committee board membership shall conform with both of the following:

(1) Represent a sufficient number of clinical specialties to adequately meet the needs of enrollees.

(2) Consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health professionals who are licensed to prescribe drugs.

(c) Members of the board shall abstain from voting on any issue in which the member has a conflict of interest with respect to the issuer or a pharmaceutical manufacturer.

(d) At least 20 percent of the board membership shall not have a conflict of interest with respect to the issuer or any pharmaceutical manufacturer.

(e) The pharmacy and therapeutics committee shall meet at least quarterly and shall maintain written documentation of the rationale for its decisions regarding the development of, or revisions to, the formulary drug list.

(f) The pharmacy and therapeutics committee shall do all of the following:

(1) Develop and document procedures to ensure appropriate drug review and inclusion.

(2) Base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other related information.

(3) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.

(4) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.

(5) Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.

(6) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.

(7) Review new United States Food and Drug Administration-approved drugs and new uses for existing drugs.

(8) Ensure that the plan's formulary drug list or lists cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and do not discourage enrollment by any group of enrollees.

(9) Ensure that the plan's formulary drug list or lists provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

(g) This section shall be interpreted consistent with federal guidance issued under paragraph (3) of subdivision (a) of Section 156.122 of Title 45 of the Code of Federal Regulations. This section shall apply to the individual, small group, and large group markets.

SEC. 4. Section 1367.42 is added to the Health and Safety Code, to read:

1367.42. (a) For plan years commencing on or after January 1, 2017, a plan that provides essential health benefits shall allow an enrollee to access prescription drug benefits at an in-network retail pharmacy unless the prescription drug is subject to restricted distribution by the United States Food and Drug Administration or requires special handling, provider

coordination, or patient education that cannot be provided by a retail pharmacy.

(b) A nongrandfathered individual or small group health plan contract may charge an enrollee a different cost sharing for obtaining a covered drug at a retail pharmacy, but all cost sharing shall count toward the plan's annual limitation on cost sharing consistent with Section 1367.006.

SEC. 5. Section 1367.205 of the Health and Safety Code is amended to read:

1367.205. (a) In addition to the list required to be provided under Section 1367.20, a health care service plan that provides prescription drug benefits and maintains one or more drug formularies shall do all of the following:

(1) Post the formulary or formularies for each product offered by the plan on the plan's Internet Web site in a manner that is accessible and searchable by potential enrollees, enrollees, providers, the general public, the department, and federal agencies as required by federal law or regulations.

(2) Update the formularies posted pursuant to paragraph (1) with any change to those formularies on a monthly basis.

(3) No later than six months after the date that a standard formulary template is developed under subdivision (b), use that template to display the formulary or formularies for each product offered by the plan.

(b) (1) By January 1, 2017, the department and the Department of Insurance shall jointly, and with input from interested parties from at least one public meeting, develop a standard formulary template for purposes of paragraph (3) of subdivision (a). In developing the template, the department and Department of Insurance shall take into consideration existing requirements for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services. To the extent feasible, in developing the template, the department and the Department of Insurance shall evaluate a way to include on the template, in addition to the information required to be included under paragraph (2), cost-sharing information for drugs subject to coinsurance.

(2) The standard formulary template shall include the notification described in subdivision (c) of Section 1363.01, and as applied to a particular formulary for a product offered by a plan, shall do all of the following:

(A) Include information on cost-sharing tiers and utilization controls, including prior authorization or step therapy requirements, for each drug covered by the product.

(B) Indicate any drugs on the formulary that are preferred over other drugs on the formulary.

(C) Include information to educate enrollees about the differences between drugs administered or provided under a health care service plan's medical benefit and drugs prescribed under a health care service plan's prescription drug benefit and about how to obtain coverage information regarding drugs that are not covered under the plan's prescription drug benefit.

(D) Include information to educate enrollees that health care service plans that provide prescription drug benefits are required to have a method for enrollees to obtain prescription drugs not listed in the health plan drug formulary if the drugs are deemed medically necessary by a clinician pursuant to Section 1367.24.

(E) Include information on which medications are covered, including both generic and brand name.

(F) Include information on what tier of the plan's drug formulary each medication is in.

(c) For purposes of this section, "formulary" means the complete list of drugs preferred for use and eligible for coverage under a health care service plan product and includes the drugs covered under the pharmacy benefit of the product.

SEC. 6. Section 10123.192 of the Insurance Code is amended to read:

10123.192. (a) A health insurer that provides prescription drug benefits and maintains one or more drug formularies shall do all of the following:

(1) Post the formulary or formularies for each product offered by the insurer on the insurer's Internet Web site in a manner that is accessible and searchable by potential insureds, insureds, providers, the general public, the department, and federal agencies as required by federal law or regulations.

(2) Update the formularies posted pursuant to paragraph (1) with any change to those formularies on a monthly basis.

(3) No later than six months after the date that a standard formulary template is developed under subdivision (b), use that template to display the formulary or formularies for each product offered by the insurer.

(b) (1) By January 1, 2017, the department and the Department of Managed Health Care shall jointly, and with input from interested parties from at least one public meeting, develop a standard formulary template for purposes of paragraph (3) of subdivision (a). In developing the template, the department and Department of Managed Health Care shall take into consideration existing requirements for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services. To the extent feasible, in developing the template, the department and the Department of Managed Health Care shall evaluate a way to include on the template, in addition to the information required to be included under paragraph (2), cost-sharing information for drugs subject to coinsurance.

(2) The standard formulary template shall include a notification that the presence of a drug on the insurer's formulary does not guarantee that an insured will be prescribed that drug by his or her prescribing provider for a particular medical condition. As applied to a particular formulary for a product offered by an insurer, the standard formulary template shall do all of the following:

(A) Include information on cost-sharing tiers and utilization controls, including prior authorization or step therapy requirements, for each drug covered by the product.

(B) Indicate any drugs on the formulary that are preferred over other drugs on the formulary.

(C) Include information to educate insureds about the differences between drugs administered or provided under a health insurer's medical benefit and drugs prescribed under a health insurer's prescription drug benefit and about how to obtain coverage information about drugs that are not covered under the health insurer's prescription drug benefit.

(D) Include information to educate insureds that health insurers that provide prescription drug benefits are required to have a method for insureds to obtain prescription drugs not listed in the health insurer's drug formulary if the drugs are deemed to be medically necessary by a clinician pursuant to Section 1367.24 of the Health and Safety Code, as required by clause (iv) of subparagraph (A) of paragraph (2) of subdivision (a) of Section 10112.27.

(E) Include information on which medications are covered, including both generic and brand name.

(F) Include information on what tier of the health insurer's drug formulary each medication is in.

(c) The commissioner may adopt regulations as may be necessary to carry out the purposes of this section. In adopting regulations, the commissioner shall comply with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(d) For purposes of this section, "formulary" means the complete list of drugs preferred for use and eligible for coverage under a health insurance product and includes the drugs covered under the pharmacy benefit of the product.

SEC. 7. Section 10123.193 is added to the Insurance Code, to read:

10123.193. (a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered policy of health insurance that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section. The cost-sharing limits established by this section apply only to outpatient prescription drugs covered by the policy that constitute essential health benefits, as defined by Section 10112.27.

(c) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this part.

(d) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs.

(e) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health insurer shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for insureds with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a policy of health insurance shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(3) Any limitation or utilization management shall be consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

(f) (1) With respect to an individual or group policy of health insurance subject to Section 10112.28, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars (\$250), except as provided in paragraphs (2) and (3).

(2) With respect to products with actuarial value at or equivalent to the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars (\$500), except as provided in paragraph (3).

(3) For a policy of health insurance that is a “high deductible health plan” under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision shall apply only once an insured’s deductible has been satisfied for the year.

(4) For a nongrandfathered individual or small group policy of health insurance, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.

(5) For purposes of paragraphs (1) and (2), “any other form of cost sharing” shall not include deductible.

(g) (1) If a policy of health insurance offered, sold, or renewed in the nongrandfathered individual or small group market maintains a drug formulary grouped into tiers that includes a fourth tier, a policy of health insurance shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost.

(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.

(D) Tier four shall consist of drugs that are biologics, drugs that the FDA or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the insured to have special training or clinical monitoring for self-administration, or drugs that cost the health insurer more than six hundred dollars (\$600) net of rebates for a one-month supply.

(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the insurer shall take into account the other provisions of this section and this part.

(3) A policy of health insurance may maintain a drug formulary with fewer than four tiers.

(4) This section shall not be construed to limit a health insurer from placing any drug in a lower tier.

(h) This section shall not be construed to require a health insurer to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

(i) A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(j) In the provision of outpatient prescription drug coverage, a health insurer may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this part.

(k) This section shall remain in effect only until January 1, 2020, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2020, deletes or extends that date.

SEC. 8. Section 10123.193 is added to the Insurance Code, to read:

10123.193. (a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered policy of health insurance that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section.

(c) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this part.

(d) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs.

(e) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health insurer shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for insureds with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a policy of health insurance shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(3) Any limitation or utilization management shall be consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

(f) This section shall not be construed to require a health insurer to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

(g) A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(h) In the provision of outpatient prescription drug coverage, a health insurer may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this part.

(i) This section shall become operative on January 1, 2020.

SEC. 9. Section 10123.201 is added to the Insurance Code, to read:

10123.201. (a) A policy of health insurance that covers outpatient prescription drugs shall cover medically necessary drugs. The policy may provide for step therapy and prior authorization consistent with Section

1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section.

(b) (1) Commencing January 1, 2017, an insurer shall maintain a pharmacy and therapeutics committee that shall be responsible for developing, maintaining, and overseeing any drug formulary list. If the insurer delegates responsibility for the formulary to any entity, the obligation of the insurer to comply with this part shall not be waived.

(2) The pharmacy and therapeutics committee board membership shall conform with both of the following:

(A) Represent a sufficient number of clinical specialties to adequately meet the needs of insureds.

(B) Consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health professionals who are licensed to prescribe drugs.

(3) Members of the board shall abstain from voting on any issue in which the member has a conflict of interest with respect to the issuer or a pharmaceutical manufacturer.

(4) At least 20 percent of the board membership shall not have a conflict of interest with respect to the issuer or any pharmaceutical manufacturer.

(5) The pharmacy and therapeutics committee shall meet at least quarterly and shall maintain written documentation of the rationale for its decisions regarding the development of, or revisions to, the formulary drug list.

(6) The pharmacy and therapeutics committee shall do all of the following:

(A) Develop and document procedures to ensure appropriate drug review and inclusion.

(B) Base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other related information.

(C) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.

(D) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.

(E) Evaluate and analyze treatment protocols and procedures related to the insurer's formulary at least annually.

(F) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.

(G) Review new United States Food and Drug Administration-approved drugs and new uses for existing drugs.

(H) Ensure the insurer's formulary drug list or lists cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and does not discourage enrollment by any group of insureds.

(I) Ensure the insurer's formulary drug list or lists provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

(7) This subdivision shall be interpreted consistent with federal guidance issued under paragraph (3) of subdivision (a) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall apply to the individual, small group, and large group markets.

(c) (1) A health insurer may impose prior authorization requirements on prescription drug benefits, consistent with the requirements of this part.

(2) (A) When there is more than one drug that is appropriate for the treatment of a medical condition, a health insurer may require step therapy.

(B) In circumstances where an insured is changing policies, the new policy shall not require the insureds to repeat step therapy when that insured is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the insured's condition. Nothing in this section shall preclude the new policy from imposing a prior authorization requirement pursuant to subdivision (a) for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former policy, or preclude the prescribing provider from prescribing another drug covered by the new policy that is medically appropriate for the insured.

(3) An insurer shall provide coverage for the medically necessary dosage and quantity of the drug prescribed for the treatment of a medical condition consistent with professionally recognized standards of practice.

(4) For plan years commencing on or after January 1, 2017, an insurer that provides essential health benefits shall allow an insured to access prescription drug benefits at an in-network retail pharmacy unless the prescription drug is subject to restricted distribution by the United States Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. A nongrandfathered individual or small group health insurer may charge an insured a different cost sharing for obtaining a covered drug at a retail pharmacy, but all cost sharing shall count toward the policy's annual limitation on cost sharing consistent with Section 10112.28.

(d) Every health insurer that provides prescription drug benefits shall maintain all of the following information, which shall be made available to the commissioner upon request:

(1) The complete drug formulary or formularies of the insurer, if the insurer maintains a formulary, including a list of the prescription drugs on the formulary of the insurer by major therapeutic category with an indication of whether any drugs are preferred over other drugs.

(2) Records developed by the pharmacy and therapeutic committee of the insurer, or by others responsible for developing, modifying, and overseeing formularies, including medical groups, individual practice associations, and contracting pharmaceutical benefit management companies, used to guide the drugs prescribed for the insureds of the insurer, that fully describe the reasoning behind formulary decisions.

(3) Any insurer arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, contracting pharmaceutical benefit management companies, or other entities that are associated with activities of the insurer to encourage formulary compliance or otherwise manage prescription drug benefits.

(e) If an insurer provides prescription drug benefits, the commissioner shall, as part of its market conduct examination, review the performance of the insurer in providing those benefits, including, but not limited to, a review of the procedures and information maintained pursuant to this section, and describe the performance of the insurer as part of its report issued as part of its market conduct examination.

(f) The commissioner shall not publicly disclose any information reviewed pursuant to this section that is determined by the commissioner to be confidential pursuant to state law.

(g) For purposes of this section, the following definitions shall apply:

(1) “Authorization” means approval by the health insurer to provide payment for the prescription drug.

(2) “Step therapy” means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.

(h) Nonformulary prescription drugs shall include any drug for which an insured’s copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug, except as otherwise provided by law or regulation.

(i) Nothing in this section shall be construed to affect an insured’s or policyholder’s eligibility to submit a complaint to the department for review or to apply to the department for an independent medical review under Article 3.5 (commencing with Section 10169).

(j) Nothing in this section shall be construed to restrict or impair the application of any other provision of this part.

SEC. 10. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.